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[RUSH] **MESSAGE:** There are two lines of continuing data on the bib data sheet but none present in the specification.

Thank You
NGB

[XRUSH] **RESPONSE:** Done

INITIALS:

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REV 10/04

Self-emulsifying Formulations of Fenofibrate and/or Fenofibrate Derivatives with Improved Oral Bioavailability and/or Reduced Food Effect

This application is a continuation-in-part of 10324953 filed Dec. 20, 2002 which claims benefit of 60/392791 filed June 28, 2002.

FIELD OF THE INVENTION

The present invention relates to a non-aqueous self–emulsifying oral pharmaceutical formulations of fenofibrate or fenofibrate derivatives having an improved oral bioavailability and/or reduced food effect when compared to a commercial available formulation.

BACKGROUND OF THE INVENTION

Fenofibrate is a fibrate used in the treatment of endogenous hyperlipidaemias, hypercholesterolaemias and hypertriglyceridaemias in adults. The preparation of fenofibrate is disclosed in US patent. No. 4,058,552. Fenofibric acid, the active metabolite of fenofibrate, produces reductions in total cholesterol, LDL cholesterol, apolipoprotein B, total triglycerides and triglyceride rich lipoprotein (VLDL) in treated patients. Also, treatment with fenofibrate results in increases in high-density lipoprotein (HDL) and apoproteins apoAI and apoAII. Prolonged treatment with fenofibrate at the rate of 300 to 400 mg per day makes it possible to obtain a reduction in total cholesterol of 20 to 25% and a reduction in the levels of triglycerides of 40 to 50%. It thus opposes the development of arteriosclerosis. The customary adult fenofibrate dosage is three gelatin capsules per day, each containing 100 mg of fenofibrate. It is known that fenofibrate absorption variations are observed depending on whether the drug was ingested with a high or low fat meal (Atkins J.C. and D. Faulds (1997) Drugs 54(4) 615 – 633).